

# **U.S. Department of Energy Orders Self-Study Program**



**DOE O 414.1C**  
QUALITY ASSURANCE

**NATIONAL NUCLEAR SECURITY ADMINISTRATION  
LEARNING AND CAREER DEVELOPMENT DEPARTMENT**

Change No: 2  
DOE O 414.1C  
Level: Familiar  
Date: 12/1/08

## DOE O 414.1C, QUALITY ASSURANCE FAMILIAR LEVEL

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### OBJECTIVES

Given the familiar level of this module and the resources listed below, you will be able to do the following:

1. State the objectives of DOE O 414.1C, *Quality Assurance*.
2. Define the following terms:
  - graded approach
  - safety system software
  - suspect/counterfeit items (S/CI)
  - quality assurance (QA)
3. State the responsibilities of the field element manager (FEM) for QA.
4. State the requirements of a quality assurance program (QAP).
5. Discuss the corrective action management program (CAMP).
6. Discuss the S/CI prevention process.

**Note: If you think that you can complete the practice at the end of this level without working through the instructional material and/or the examples, complete the practice now. The course manager will check your work. You will need to complete the practice in this level successfully before taking the criterion test.**

### RESOURCES

DOE O 414.1C, *Quality Assurance*, 6/17/05.

DOE G 414.1-2A *Quality Assurance Management System Guide for Use with 10 CFR 830 Subpart A, Quality Assurance Requirements, and DOE O 414.1C, Quality Assurance*, 6/17/05.

## INTRODUCTION

The familiar level of this module is designed to summarize the basic information in DOE O 414.1C, *Quality Assurance*. In this module we will discuss the important elements of DOE O 414.1C and the accompanying guide, DOE G 414.1-2A *Quality Assurance Management System Guide for Use with 10 CFR 830 Subpart A, Quality Assurance Requirements, and DOE O 414.1C, Quality Assurance*. The module is divided into two sections. Section one includes statements of objectives, requirements. Section two provides an overview of the following quality program elements: S/CI prevention process, corrective action management program, and software quality assurance. Section three discusses the important elements of DOE G 414.1-2A. An example and a practice have been provided in the module to help familiarize you with the material. The practice will help prepare you for the criterion test. The information provided will meet the relevant requirements in the following DOE Functional Area Qualification Standards:

- DOE-STD-1173-2003, *Criticality Safety*
- DOE-STD-1170-2007, *Electrical Safety and Systems Oversight*
- DOE-STD-1156-2002, *Environmental Compliance*
- DOE-STD-1157-2002, *Environmental Restoration*
- DOE-STD-1181-2004, *Facility Maintenance Management*
- DOE-STD-1151-2002, *Facility Representative*
- DOE-STD-1146-2007, *General Technical Base*
- DOE-STD-1138-2007, *Industrial Hygiene*
- DOE-STD-1162-2002, *Instrumentation and Controls*
- DOE-STD-1150-2002, *Quality Assurance*
- DOE-STD-1174-2003, *Radiation Protection*
- DOE-STD-1172-2003, *Safety Software Quality Assurance*
- DOE-STD-1175-2006, *Senior Technical Safety Manager*
- DOE-STD-1178-2004, *Technical Program Manager*
- DOE-STD-1179-2004, *Technical Trainer*
- DOE-STD-1155-2002, *Transportation and Traffic Management*
- DOE-STD-1159-2003, *Waste Management*
- DOE-STD-1025-2008, *Weapon Quality Assurance*

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Completion of this module also meets certain requirements associated with the DOE Facility Representative (FR) Program and the DOE Intern Program. The information contained in this module addresses specific requirements and as such does not include the entire text of the source document. Before continuing, you should obtain a copy of the Order and its accompanying manuals. Copies of the DOE Directives are available at <http://www.directives.doe.gov/> or through the course manager.

## SECTION 1 – INTRODUCTION

### OBJECTIVES

DOE O 414.1B was developed to ensure the quality of the DOE products and services that will meet or exceed customer expectations for all work based on the following principles:

- That quality is assured and maintained through a single, integrated, effective quality assurance program (i.e., management system).
- That management support for planning, organization, resources, direction, and control is essential to QA.
- That performance and quality improvement require thorough, rigorous assessment and corrective action.
- That workers are responsible for achieving and maintaining quality.
- That environmental, safety, and health risks and impacts associated with work processes can be minimized while maximizing reliability and performance of work products.
- That quality process requirements are implemented under a QAP for the control of S/CIs, safety issue corrective actions, and safety software.

### RESPONSIBILITIES

In this section, we will discuss the major responsibilities of FEMs associated with DOE O 414.1C. A complete list of responsibilities is available in the Order.

- Develop and implement approved QAPs governing the work under their purview.
- Submit QAPs to the appropriate Secretarial Officer (SO) for review, resolution of differences of opinion, and approval.
- Review and approve new and revised QAPs for contractors.
- Perform independent assessments of contractor organizations to evaluate the adequacy and QAP implementation effectiveness.
- Periodically report management assessment results to their organizations' SOs describing the effectiveness of field element and contractor QA implementation.
- Prepare and implement a corrective action plan (CAP) to address all findings in the Corrective Action Management Program assessment report, and enter, track, and report the status of the CAP in the Corrective Action Tracking System (CATS).

- Complete the CAP and conduct followup review on the effectiveness of the corrective actions in resolving and preventing recurrence of all findings. Approve the effectiveness review report and followup report recommendations.

## REQUIREMENTS

### **Quality Assurance Program Requirements**

Each DOE organization must develop and implement a QAP that does the following:

- Implements QA criteria using a graded approach and describing how the criteria and graded approach are applied.
- Uses national or international consensus standards where practicable and consistent with contractual or regulatory requirements and identifies the standards used.
- Applies additional standards, where practicable and consistent with contractual or regulatory requirements and as necessary to address unique/specific work activities.
- Integrates quality management system requirements with other quality or management system requirements in DOE directives and external requirements.

### **Quality Assurance Criteria**

Quality Assurance Criteria. The QAP must address the following management, performance, and assessment criteria.

- Management/Criterion 1—Program
  - Establish an organizational structure, functional responsibilities, levels of authority, and interfaces for those managing, performing, and assessing work.
  - Establish management processes, including planning, scheduling, and providing resources for work.
- Management/Criterion 2—Personnel Training and Qualification
  - Train and qualify personnel to be capable of performing assigned work.
  - Provide continuing training to personnel to maintain job proficiency.
- Management/Criterion 3—Quality Improvement
  - Establish and implement processes to detect and prevent quality problems.
  - Identify, control, and correct items, services, and processes that do not meet established requirements.

- Identify the causes of problems, and include prevention of recurrence as a part of corrective action planning.
- Review item characteristics, process implementation, and other quality-related information to identify items, services, and processes needing improvement.
- Management/Criterion 4—Documents and Records
  - Prepare, review, approve, issue, use, and revise documents to prescribe processes, specify requirements, or establish design.
  - Specify, prepare, review, approve, and maintain records.
- Performance/Criterion 5—Work Processes
  - Perform work consistent with technical standards, administrative controls, and hazard controls adopted to meet regulatory or contract requirements using approved instructions, procedures, etc.
  - Identify and control items to ensure their proper use.
  - Maintain items to prevent their damage, loss, or deterioration.
  - Calibrate and maintain equipment used for process monitoring or data collection.
- Performance/Criterion 6—Design
  - Design items and processes using sound engineering/scientific principles and appropriate standards.
  - Incorporate applicable requirements and design bases in design work and design changes.
  - Identify and control design interfaces.
  - Verify/validate the adequacy of design products using individuals or groups other than those who performed the work.
  - Verify/validate work before approval and implementation of the design.
- Performance/Criterion 7—Procurement
  - Procure items and services that meet established requirements and perform as specified.
  - Evaluate and select prospective suppliers on the basis of specified criteria.
  - Establish and implement processes to ensure that approved suppliers continue to provide acceptable items and services.

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- Performance/Criterion 8—Inspection and Acceptance Testing
  - Inspect and test specified items, services, and processes using established acceptance and performance criteria.
  - Calibrate and maintain equipment used for inspections and tests.
- Assessment/Criterion 9—Management Assessment
  - Ensure that managers assess their management processes and identify and correct problems that hinder the organization from achieving its objectives.
- Assessment/Criterion 10—Independent Assessment
  - Plan and conduct independent assessments to measure item and service quality and the adequacy of work performance and to promote improvement.
  - Establish sufficient authority and freedom from line management for independent assessment teams.
  - Ensure that persons conducting independent assessments are technically qualified and knowledgeable in the areas to be assessed.

**Note: You do not have to do example 1 on the following pages, but it is a good time to check your skill and knowledge of the information covered. You may do example 1 or go to section 2.**



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4. What is the quality criteria for management assessments?

**Note: When you are finished, compare your answers to those contained in the example 1 self-check. When you are satisfied with your answers, go to section 2.**

### EXAMPLE 1 SELF-CHECK

1. What are four responsibilities of FEMs for quality assurance?

**Note: Any four the following comprise a complete answer**

- Develop and implement approved QAPs governing the work under their purview.
  - Submit QAPs to the appropriate Secretarial Officer (SO) for review, resolution of differences of opinion, and approval.
  - Review approve new and revised QAPs for contractors.
  - Perform independent assessments of contractor organizations to evaluate the adequacy and QAP implementation effectiveness.
  - Periodically report management assessment results to their organizations' SOs describing the effectiveness of field element and contractor QA implementation.
  - Prepare and implement a corrective action plan (CAP) to address all findings in the Corrective Action Management Program assessment report, and enter, track, and report the status of the CAP in the Corrective Action Tracking System (CATS).
  - Complete the CAP and conduct followup review on the effectiveness of the corrective actions in resolving and preventing recurrence of all findings. Approve the effectiveness review report and followup report recommendations.
2. What are the objectives of DOE O 414.1C?

DOE O 414.1B was developed to ensure the quality of the DOE products and services that will meet or exceed customer expectations for all work based on the following principles:

- That quality is assured and maintained through a single, integrated, effective quality assurance program (i.e., management system).
- That management support for planning, organization, resources, direction, and control is essential to QA.
- That performance and quality improvement require thorough, rigorous assessment and corrective action.
- That workers are responsible for achieving and maintaining quality.

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- That environmental, safety, and health risks and impacts associated with work processes can be minimized while maximizing reliability and performance of work products.
  - That quality process requirements are implemented under a QAP for the control of S/CIs, safety issue corrective actions, and safety software.
3. What are the requirements for a QAP as described in DOE O 414.1C.

Each DOE organization must develop and implement a QAP that does the following.

- Implements QA criteria using a graded approach and describing how the criteria and graded approach are applied.
  - Uses national or international consensus standards where practicable and consistent with contractual or regulatory requirements and identifies the standards used.
  - Applies additional standards, where practicable and consistent with contractual or regulatory requirements and as necessary to address unique/specific work activities.
  - Integrates quality management system requirements with other quality or management system requirements in DOE directives and external requirements.
4. What is the quality criteria for management assessments?
- Ensure that managers assess their management processes and identify and correct problems that hinder the organization from achieving its objectives.

## **SECTION 2 – QUALITY PROGRAM IMPLEMENTATION**

This section of the module summarizes the suspect/counterfeit items (S/CI) prevention process, the CAMP, and the safety software quality program requirements discussed in DOE O 414.1C.

### **SUSPECT/COUNTERFEIT ITEMS (S/CI) PREVENTION PROCESS**

An S/CI prevention process must be developed and implemented as a part of the organization's QAP and commensurate with the facility/activity hazards and mission impact. The QAP must be applied to identifying and analyzing S/CIs, removing them, and preventing S/CIs from being supplied to DOE/NNSA and its contractors.

The DOE Office of Environment, Safety, and Health provides the following as a service to DOE and its contractors:

- collecting, analyzing, and disseminating S/CI information;
- notifying SOs when specific actions must be taken to investigate and resolve S/CI quality and safety issues; and
- tracking and reporting the status of corrective actions.

#### **S/CI Quality Management System Requirements**

The QAP must include the management position responsible for S/CI prevention and address the following:

- preventing the introduction and use of S/CIs through engineering involvement, design, procurement, testing, inspection, maintenance, evaluation, disposition, reporting, trend analysis, and lessons learned work process controls;
- training and informing managers, supervisors, and workers on S/CI processes and controls (including prevention, detection, and disposition of S/CIs); and
- identifying and disposing of S/CIs on site.

#### **Work Process Controls**

Work processes must be developed and implemented using available S/CI information and include the following:

- engineering involvement in the development of procurement specifications; during inspection and testing; and when replacing, maintaining, or modifying equipment;
- procurement processes that prevent introduction of S/CIs;

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- inspection, identification, evaluation and disposition of S/CIs that have been installed in safety applications and other applications that create potential hazards;
- engineering evaluations and disposition of S/CIs installed in safety applications/systems or in applications that create potential hazards. Evaluations must consider potential risks to the public and workers cost/benefit impact, and a schedule for replacement;
- ensuring that S/CIs in nonsafety applications identified during routine maintenance and/or inspection are reported, evaluated, and dispositioned to prevent future use in safety applications;
- contacting the DOE Inspector General before destroying or disposing of S/CIs and their documentation to determine whether to retain them for criminal investigation or litigation;
- testing procured or installed S/CIs as necessary using approved engineering test methods;
- reporting S/CIs as per DOE O 231.1A, *Environment, Safety, and Health Reporting*, and DOE O 221.1A, *Reporting Fraud, Waste, and Abuse to the Office of Inspector General*; and
- conducting trend analysis and issuing lessons learned reports for use in improving the S/CI prevention.

## CORRECTIVE ACTION MANAGEMENT PROGRAM

The objective of the CAMP is to prescribe process requirements and responsibilities for DOE line managers to perform corrective actions that effectively resolve safety issues.

### **Requirements**

Reporting Findings. The assessing organization submits the final assessment report within 10 calendar days of issuance to the FEM, the SO, and the Office of Environment, Safety, and Health.

CAP Development, Approval, and Review. The FEM in consultation with the appropriate SO must prepare a comprehensive CAP in writing to address assessment findings and field and Headquarters corrective actions for each finding. Guidance for implementing these

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requirements is outlined in DOE G 450.4-1B, *Integrated Safety Management System Guide*, volume 2, appendix G.

The CAP must be prepared on a schedule that will allow for review and approval by the SO or designee within 60 calendar days from the date the transmittal forwarding the formal final assessment/investigation report was issued.

The SO or designee must forward copies of an approved CAP to the organization that conducted the assessment for review and to the Office of Environment, Safety, and Health (ES&H).

Tracking and Reporting Implementation. The FEM

- is responsible for implementing the approved CAP and ensuring timely and effective completion of all corrective actions;
- must enter, track, and report the status of the CAP and associated corrective actions to closure in the DOE CATS database;
- must enter CAP corrective action data as stated in the approved CAP for each finding in CATS within 10 working days after approval; and
- must ensure that all corrective actions are tracked and their status reported to completion and verification.

Completion of each corrective action must be annotated in the CATS descriptive status and completion date fields.

Other sites/organizations that forwarded portions of the CAP and corrective actions to the lead FEM must track and provide the FEM updates of their portions of the CAP and corrective actions to completion and verification within the timeframes specified in DOE O 414.1C.

The FEM must update the CAP status field and corrective action descriptive status fields on a frequent basis and enter the date at the beginning of each update.

Requests for CAP changes in CATS must be approved by the SO who approved the CAP and submitted as outlined in the CATS user's guide.

Information in CATS will be used to provide periodic status reports to assist senior DOE

management in monitoring the status of the CAMP.

Corrective Action Effectiveness Review. Evaluation of findings and implementation of corrective actions is conducted to correct the underlying causes for the finding. In some instances completed corrective actions have failed to effectively resolve or prevent recurrence of the same or similar assessment findings.

Purpose.

Evaluation of findings and implementation of corrective actions is conducted to correct the underlying causes for the finding. In some instances completed corrective actions have failed to effectively resolve or prevent recurrence of the same or similar assessment findings.

Effectiveness reviews will

- determine whether completed corrective actions have or have not effectively resolved and prevented recurrence of the same or similar findings at the performance level;
- identify additional actions necessary to effectively resolve the findings and prevent recurrence; and
- collect effectiveness data for subsequent analyses and sharing of lessons learned.

Reporting and Followup. A formal report documenting the results of the effectiveness review must be completed and approved by the FEM no later than 6 months after the CAP completion date.

Lessons Learned. At any time during the CAMP process, the FEM must develop and implement lessons learned identified from the assessment findings, corrective actions in response to the findings, and results of corrective action effectiveness reviews, as applicable.

Corrective Action Management Team. The CAM Team, a cross-organizational working group of representatives from Headquarters and field offices, must be maintained to support and coordinate effective line management implementation of the CAMP.

## SAFETY SOFTWARE QUALITY ASSURANCE

Safety software quality requirements are necessary to ensure that DOE/ NNSA safety

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software in nuclear facilities performs its intended specific safety functions in relation to structures, systems, or components (SSCs) and that the classification, design, and analysis associated with nuclear facility operations is correct. These requirements complement those of 10 CFR 830 and provide detail for work associated with safety software that is conducted under the nuclear facility QAP compliant with 10 CFR 830.

For guidance in compliance with these requirements see DOE G 414.1-3, *Suspect/Counterfeit Items Guide for Use with 10 CFR 830 Subpart A, Quality Assurance Requirements*, and *DOE O 414.1B, Quality Assurance*, dated 11-3-04. The QAP must address the following for S/CI prevention:

- preventing the introduction and use of S/CIs through engineering involvement, design, procurement, testing, inspection, maintenance, evaluation, disposition, reporting, trend analysis, and lessons learned work process controls;
- training and informing managers, supervisors, and workers on S/CI processes and controls (including prevention, detection, and disposition of S/CIs);
- identifying and disposing of S/CIs on site;
- restricting the use of an S/CI to only those items that have been found acceptable through engineering analysis and formal disposition process; and
- collecting, maintaining, disseminating, and using the most accurate, up-to-date information on S/CIs and suppliers using all available sources.

<b>Note: You do not have to do example 2 on the following pages, but it is a good time to check your skill and knowledge of the information covered. You may do example 2 or go to section 3.</b>
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### **EXAMPLE 2 SELF-CHECK**

1. What services does the Office of Environment, Safety, and Health offer DOE and its contractors regarding S/CIs?

The DOE Office of Environment, Safety, and Health provides the following as a service to DOE and its contractors:

- collecting, analyzing, and disseminating S/CI information;
- notifying SOs when specific actions must be taken to investigate and resolve S/CI quality and safety issues; and
- tracking and reporting the status of corrective actions.

2. What is the objective of the CAMP?

The objective of the CAMP is to prescribe process requirements and responsibilities for DOE line managers to perform corrective actions that effectively resolve safety issues.

3. Copies of an approved CAP must be sent to what organization(s)?

Copies of an approved CAP must be sent to the organization that conducted the assessment for review and to the Office of ES&H.

### **SECTION 3 – DOE G 414.1-2A**

This guide provides information on principles, requirements, and practices used to establish and implement an effective QAP or quality management system consistent with the requirements of 10 CFR 830 Subpart A and DOE O 414.1C.

#### **THE GRADED APPROACH**

A graded approach that doesn't compromise public, employee, or facility safety or adversely impact the environment and complies with requirements, rules, and regulations must be used to implement the QAP. The graded application of facility/activity requirements is dependent on the hazards and/or level of risk associated with the activity or structures, systems, and components (SSCs) under consideration. The scope, depth, and rigor of the quality management system's application of requirements should be determined by the use of a grading process before performing the activity. The purpose of grading is to select the controls and verifications to be applied to various items and activities consistent with their importance to safety, cost, schedule, and success of the program.

Grading is encouraged if a single or uniform method of applying a requirement across a facility or activity does not add value or reduce risk. The grading process provides the flexibility to design controls that best suit the facility or activity. The grading process is not used to obtain exemptions from the requirements of the QA Rule or Order.

The grading process is used to determine the appropriate controls to address and mitigate hazards and/or risks. This process is accomplished by deliberate quality planning and is based on activity-specific or facility-specific factors such as

- the relative importance to safety, safeguards, and security;
- the magnitude of any hazard or risk involved;
- the life-cycle stage of a facility or activity;
- impact/consequences on the programmatic mission of a facility;
- the particular characteristics of a facility or activity;
- the nuclear safety classification or hazard category of the item or activity;
- adequacy of existing safety documentation;
- the relative importance of radiological and nonradiological hazards;

- complexity of products or services involved;
- performance history of a facility or activity; and
- any other relevant factors.

The first step in the grading process is to identify the hazards, and for the facility level their consequences and probability of a failure, before work begins. The second step is to identify the specific requirements and controls to be applied. The third step is to determine the depth, extent, and degree of rigor necessary in the application of the requirements and controls. The final step is to communicate and implement the selected requirements and controls and their degree of rigor by means of documented work processes (procedures, instructions, specifications, and controls). The logic, method of implementation, and basis for grading should be documented in the quality management system, periodically reviewed in light of changes that may have occurred, and if appropriate, revised to reflect those changes.

#### INTEGRATING THE SAFETY MANAGEMENT AND QUALITY MANAGEMENT SYSTEMS

The quality management system complements and is integrated with the safety management system. The quality management system provides processes and tools for ensuring that integrated safety management (ISM) system objectives are achieved. The DOE fundamental quality expectation is that all work meets established requirements. In this regard, the quality management system ensures compliance with the approved safety standards set, so that the expectation for safe work within controls is met. This also ensures that workers, the environment, and the public are reasonably protected from harm.

At the organizational or institutional level, the DOE quality and safety requirements share a management systems approach to achieving their objectives. As such, the required system documentation for each ISM system description and QAP may be integrated into a single document to describe how the organization intends to implement the requirements. In some cases, the local DOE office and contractor may determine that it is expedient to maintain both the ISM system description and the QAP. In these cases, as a minimum, the implementing mechanisms that are described in each should be integrated to the maximum extent practical, and the system description and QAP should cross-reference these procedures as applicable. For example, the processes and procedures for conducting management assessments should

be referenced in both the QAP and the ISM system description.

Some shared attributes of quality and safety management systems may include:

- expectations for implementation,
- documentation of the management system,
- clear roles and responsibilities ,
- balanced priorities (resources) ,
- feedback and improvement ,
- line management responsibility,
- competence and qualifications,
- standards and controls for work, and
- graded and tailored controls.

## DOCUMENTS AND RECORDS

Documents and records are required to effectively manage, perform, and assess work. Documents and records should include applicable requirements to indicate that work (including safety) has been properly specified and accomplished. Management should identify any documents and records that must be developed and controlled. Management is responsible to provide the resources necessary to accomplish the document and record requirements.

A document control system should be in place to control the preparation, review, approval, issue, control, and revision of documents. Documents are required by organizations, projects, or programs to control policy and administrative and/or technical information. A document may describe work to be done, data to be used at different locations or by different people, or, in changing situations, data to be controlled from time to time for reference purposes. The document control system should be established to supply the documents necessary for personnel to safely and correctly perform their assigned responsibilities. Document control systems ensure that the mechanisms developed to implement the safety management functions of DOE P 450.4 are properly prepared, controlled, and available for use.

A record contains information that is retained for its expected future value. Records should be sufficient to support technical and regulatory decisions and provide evidence that work was correctly performed. Records may be in a variety of forms (e.g., electronic, written, or

printed; microfilm; photographs; radiographs; or optical disks). Typical records include procedures, plans, and manuals; training and qualification results; acceptance test results; technical/ regulatory correspondence; operational records; design basis descriptions, design review results, design revisions, and configuration management data; and quality problem resolutions.

Records should be compiled in a records management system. The system should include provisions for specifying, preparing, reviewing, approving, disposing, and maintaining records. Records retention, protection, preservation, change, traceability, accountability, and retrievability should also be specified. The records management system should have schedules for records retention and disposition consistent with the requirements of DOE O 200.1, *Information Management Program*.

The hardware and software tools used to create and store records should be maintained to ensure that the records can be retrieved. The National Archives and Records Administration, 36 CFR, chapter XII, provides a recommended approach for maintenance of records, including electronic records management.

## DESIGN

A design process should be established that provides appropriate control of design inputs, outputs, verification, configuration and design changes, and technical and administrative interfaces. Design work should be based on sound engineering judgment, scientific principles, and applicable codes and standards. DOE O 420.1B, *Facility Safety*, identifies some of the design requirements.

The design of SSCs, software, and processes should be subject to design process controls and verification requirements appropriate to the level of risk the items present to the public, the worker, the environment, and project success. For example, selection of the applicable design control requirements for a facility should be guided by safety analyses that establish

- the identification and functions of safety SSCs;
- the significance to safety of functions performed by those SSCs; and
- the aspects critical to the performance, reliability, or programmatic requirements of the designed SSCs.

Designs should provide for appropriate acceptance, inspection, testing, and maintenance

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criteria to ensure continuing reliability and safety of the items. The designer should consider the expected use and life expectancy of the items to allow appropriate disassembly and disposal requirements to be addressed.

Design documentation should include a list of approved and controlled computer codes.

Design records should include documentation such as design inputs, calculations, and analyses; engineering reports; design outputs; design changes; design verification activities; and other documents that provide evidence that the design process was completed correctly.

## PROCUREMENT

The procurement process should ensure that items and/or services provided by suppliers meet the requirements and expectations of the end user. The procurement process should be planned and controlled to ensure that

- the end user's requirements are accurately, completely, and clearly communicated to the supplier;
- supplier, designer, and end-user requirements are met during the production phase; and
- the proper product is delivered on time and maintained until use.

Procurement processes should prevent introduction of S/CIs and provide a method to detect them before they are released for use.

The selection of procurement requirements should be commensurate with the importance of the end use of the purchased item or service. Management controls exist for DOE procurement and subcontracts through applicable DOE Orders, the Department of Energy Acquisition Regulation (the DEAR) in 48 CFR subchapters A through H, and the Federal Acquisition Regulation (FAR), in 48 CFR 970 et. seq.

The procurement process of DOE nuclear facility contractors must include a determination of the applicability of 10 CFR 830 to the supplier or subcontractor. If applicable, procurement documents and contracts for items and services provided to facilities covered by 10 CFR 830 should include a statement informing the supplier or subcontractor that it is subject to 10 CFR 830 and of the potential for enforcement actions under 10 CFR 820.

Items procured for safety applications in nuclear activities or SSCs should be either

- purchased from a supplier whose quality assurance program has been evaluated and found acceptable or
- purchased as commercial-grade items for dedication to the safety service.

Commercial-grade items intended for use in nuclear safety applications should be procured in accordance with documented processes using recognized consensus standards. Critical design characteristics should be identified by the design organization during item selection. Critical design characteristics and appropriateness of the item for use should be verified by

- testing the item,
- inspecting the item, and/or
- evaluating the supplier's ability to consistently supply the item at a level of quality that meets the safety and reliability requirements for the item.

#### INSPECTION

The procurement process should provide for identifying inspections and tests to ensure conformance with purchase requirements. Design and procurement documents should specify critical or important acceptance parameters for inspection.

Inspections should include verification that specified documentation has been provided by the supplier and that items were not damaged during shipment. Inspection may include the following methods:

- inspections of materials or equipment at the supplier's plant,
- receipt inspection of the shipped items,
- review of objective evidence such as certifications and reports, and
- verification or testing of items before or following shipment.

**YOU ARE FINISHED WITH THE FAMILIAR LEVEL OF THIS MODULE. YOU MAY PROCEED TO THE PRACTICE.**







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## DOE O 414.1C, QUALITY ASSURANCE GENERAL LEVEL

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### OBJECTIVES

Given the familiar level of this module, and a scenario, you will be able to perform the following:

1. List the key elements you would look for in the contractor's action plan to correct the situation described in the scenario.
2. State which requirements, sections, or elements of DOE O 414.1C, its associated guides, and 10 CFR 830.120–122 apply to the situation described in the scenario.

<b>Note: If you think that you can complete the practice at the end of this level without working through the instructional material and/or the examples, complete the practice now. The course manager will check your work. You will need to complete the practice in this level successfully before taking the criterion test.</b>
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### RESOURCES

DOE O 414.1C, *Quality Assurance*, 6/17/05.  
10 CFR 830.120–122, “Quality Assurance Requirements.”

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## **INTRODUCTION**

The familiar level of this module introduced the purpose and scope of DOE O 414.1C. In the general level of this module, students are asked to apply the information contained in the familiar level and the Order to a scenario related to the Order. Please refer to the resources listed on the previous page to make your analysis and answer the questions.

<b>Note: You do not have to do the example on the following page, but it is a good time to check your skill and knowledge of the information covered. You may do the example or go on to the practice.</b>
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## **EXAMPLE SCENARIO**

Please review the scenario, and then answer the questions that follow.

### **SCENARIO**

During troubleshooting of electrical power systems associated with a core sampling truck, it was discovered that wiring from a portable 37.5 KVA transformer to the power supply leads coming from the transformer were improperly connected.

It was determined that fabrication of the transformer distribution wiring resulted in a ground wire being improperly connected to a 120-122 volt hot lead. When the power supply leads coming from the transformer were connected to the water supply truck, the truck platform, normally connected to ground, was energized by 120-122 volts.

No personnel injuries resulted from this event.

An investigation of the situation revealed the following:

- The power cable used to route power from the skid-mounted transformer was improperly fabricated. When one end of the cable was plugged into the transformer, the green, or ground, lead of the cable connected to the black, or hot, lead coming from the transformer. This resulted in the ground wire carrying current from the transformer to the water truck's grounding system.
- Lack of supervision was identified as a contributing cause that resulted in the fabrication of parts that were not consistent with the design documents. Inadequate design documents were also identified as a contributing cause. The reels specified did not allow the equipment ground to be continuous through the circuit. Additionally, male plugs on the end of the cables were specified where the female socket should have been. Another factor was that the design document did not specify quality control's (QC's) involvement.
- The acceptance test procedure did not specify testing of the complete system and, therefore, none was performed. This procedure did not specify acceptance test criteria or final inspections.
- The cable used to route power from the transformer to the water truck was not tested to ensure reliability.

The following actions were taken by the contractor:

- The portable transformer was taken out of service.
- A critique was held with operations, maintenance, safety and engineering to determine immediate corrective actions necessary to prevent the use of the portable electrical distribution equipment.
- Two unused, similar transformers manufactured by a different group were also removed from service, pending completion of corrective actions.
- An inspection of all three transformers was completed, documented, and photos were taken.
- A restart team was formed to review all electrical fabrication work affected by the stop work order. The focus of the review was to ensure work packages are technically complete and contain sufficient safeguards to ensure quality and safety of the delivered product.
- A supervisor with electrical experience was assigned to supervise work in the fabrication shops.
- Requirements were established that all future electrical work performed by site fabrication services will require the following:
  - a design review,
  - an approved QC plan,
  - a post-fabrication inspection,
  - a functional test,
  - formal customer acceptance of work accomplished, and
  - customer notification of final inspection and testing so they can participate.

The DOE requirements that apply to this scenario are

- Train and qualify personnel to be capable of performing assigned work. (DOE O 414.1C, page 4)
  - Design items and processes using sound engineering/scientific principles and appropriate standards. (DOE O 414.1C, page 5)
1. Is the contractor's action plan correct? If not, state what should have been done.
  2. Were the correct DOE documents or requirements cited? If not, state the correct documents or requirements.

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Write your answers below and then compare them to the ones contained in the example self-check.

**EXAMPLE SELF-CHECK**

Your answers do not have to match the following exactly. You may have added more corrective actions or cited other requirements from the Order that apply. To be considered correct, your answer must include at least the following:

The contractor took all the appropriate actions.

The DOE requirements cited were correct, but not complete. Additional requirements are

- Prepare, review, approve, issue, use, and revise documents to prescribe processes, specify requirements, or establish design. (DOE O 414.1C, page 5)
- Perform work consistent with technical standards, administrative controls, hazard controls adopted to meet regulatory or contract requirements using approved instructions, procedures, etc. (DOE O 414.1C, page 5)
- Inspect and test specified items, services, and processes using established acceptance and performance criteria. (DOE O 414.1C, page 6)

## **PRACTICE**

This practice is required if your proficiency is to be verified at the general level. The practice will prepare you for the criterion test. You will need to refer to the Orders and the implementation guide to answer the questions in the practice correctly. The practice and criterion test will also challenge additional analytical skills that you have acquired in other formal and on-the-job training.

Please review the scenario and answer the questions that follow.

## **SCENARIO**

During observation of a critical lift of a retrieved waste box, a facility representative (FR) observed that the metal platform on which the waste box was staged had rust and corrosion near the lift points. These metal platforms are used as a rigid base to assist in the movement of retrieved waste boxes that have unknown structural integrity. The metal platforms are part of the lifted load for movement and storage of retrieved waste boxes, and have manufacturer installed lift points. The platforms are designed for use in commercial applications for movement of containers for overseas transport.

Based on observed corrosion, the FR questioned the adequacy of design specifications and inspection processes used for the platforms prior to use. Site management verified that the platforms are constructed to International Standards Organization Standard 1496. Riggers inspect the platform lift points prior to performing a critical lift. Inspection criteria relative to the integrity of the entire platform, however, had not been developed.

1. List the key elements you would look for in the contractor's action plan to correct the situation described in the scenario.
2. State which requirements of DOE O 414.1C apply to the situation described in the scenario.

Write your answer on the next page and then take the completed practice to the course manager for review.

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**Note: The course manager will check your practice and verify your success at the general level. When you have successfully completed this practice, the course manager will give you the criterion test.**